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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,853	10/23/2003	Diane McGhee	20520/1 (S-8135-CIP-2)	6726

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EXAMINER

WOODWARD, ANA LUCRECIA

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,853

Applicant(s)

MCGHEE, DIANE

Examiner

Ana L. Woodward

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/09/2004, 6/16/2005
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 5, 13, 14, 18, 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-4 is/are allowed.
- 6) ☒ Claim(s) 6-12, 15-17 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. .
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/9/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (PVP and silver protein species elected without traverse) in the reply filed on June 16, 2005 is acknowledged. The traversal is on the ground(s) that the claims of Group II encompass additional species of the compositions of Group I. This is not found persuasive because applicants have not submitted evidence or identified such evidence now of record showing the species to be obvious variants or clearly admitted on the record that this is the case.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 5, 13, 14, 18 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 16, 2005.

Claim Rejections - 35 USC § 112

3. Claims 1-4, 6-12 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 9, the "hydrophilic polymer" does not distinguish over the "isocyanate-terminated prepolymer" as the latter has the ability to react with water. Accordingly, said components read on one and the same composition entity.

In claims 1 and 9, the metes and bounds of the "pharmacological additive" are indeterminate in scope.

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In claims 4 and 12, "propolyacrylate" is indefinite as to scope and meaning.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-4, 6-12 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 4,769,013 (Lorenz et al) in combination with U.S. 5,558,900 (Fan et al) and U.S. 4,467,073 (Creasy).

Lorenz et al disclose coating compositions for medical devices comprising a polyurethane, reading on the presently claimed prepolymer, complexed with polyvinylpyrrolidone, reading on the presently claimed hydrophilic polymer, and a bio-effecting agent, reading on the presently claimed pharmacological additive. The complex can be obtained by mixing an isocyanate prepolymer with polyvinylpyrrolidone in a solvent, such as applicant's ethyl lactate (examples). Suitable bio-effecting agents include species from applicant's preferred additive list (column 4, lines 39-43, column 8, lines 8-18). Lorenz et al does not expressly disclose the use of the presently claimed solvent.

Fan et al disclose lubricious coatings for medical devices comprising 1) a poly(ethylene oxide) polymer, optionally in admixture with other water-soluble polymers, such as polyvinyl pyrrolidone, reading on the presently claimed hydrophilic polymer 2) an isocyanate-terminated prepolymer, reading on the presently claimed prepolymer and 3) inert organic solvents and mixtures thereof, embracing the presently claimed solvent and alkylester of a carboxylic acid.

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Suitable solvents include dimethylformamide, tetrahydrofuran and ethyl acetate (column 4, lines 21-30). Other suitable additives include antimicrobial agents, anti-thrombogenic agents and antibiotics, reading on the presently claimed pharmacological additive (column 2, lines 63-67). While Fan et al disclose both the solvent and the alkylester of the present claims, they do not expressly exemplify mixtures thereof.

Creasy discloses coating compositions for medical devices comprising polyvinylpyrrolidone, isocyanate prepolymer, solvents and biocides. Suitable solvents include alkylesters such as ethyl lactate and ethyl acetate as well as methylene chloride (column 2, lines 62-66). While Creasy discloses both the solvent and the alkylester of a carboxylic acid of the present claims, he does not expressly exemplify mixtures thereof.

The disclosures of the cited references are highly similar both in terms of materials and purpose such that one having ordinary skill in the art would readily understand that the teachings in one are relevant to the others. Accordingly, it would have been obvious to one having ordinary skill in the art to have employed a solvent system comprising a combination of applicants' solvent and alkylester of a carboxylic acid as the solvent component for the polyvinylpyrrolidone and isocyanate prepolymer of the prior art with the reasonable expectation of success. Each of said applicants' materials is taught by the prior art to be useful for the same purpose. Accordingly, it would have obvious to combine said two materials in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. Absent evidence of unusual or unexpected results relative to the combined use of the solvent and the alkylester of a

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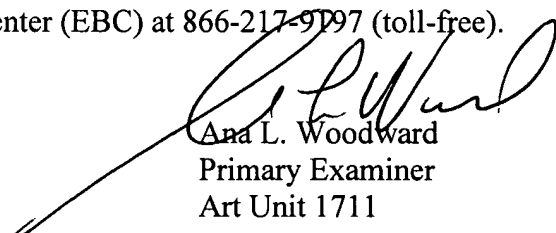
carboxylic acid of the present claims, no patentability can be seen in the presently claimed subject matter.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana L. Woodward whose telephone number is (571) 272-1082. The examiner can normally be reached on Monday-Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ana L. Woodward
Primary Examiner
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